DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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February 20, 2015

Güenter Bissinger Medizintechnik GmbH
Matthias Bissinger
Managing Director
Hans-Theisen-Straße 1
79331 Teningen Baden-Wuerttemberg
Germany

Re: K150024
Trade/Device Name: Monopolar Cables
Regulation Number: 21 CFR 878.4400
Regulation Name: Electrosurgical cutting and coagulation device and accessories
Regulatory Class: Class II
Product Code: GEI
Dated: December 1, 2014
Received: January 7, 2015

Dear Mr. Bissinger:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Jennifer R. Stevenson -S

For Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
-- K150024

Device Name
Monopolar Cables

Indications for Use *(Describe)*
Cables for electrosurgery are designed to conduct electrical power from the output of a high-frequency electrosurgical generator to the electrosurgical instrument.
Do not exceed a maximum output of 6250 Vp of your generator.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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K 150024

VOLUME 006

510(k) Summary

DATE OF APPLICATION: 2014-12-01

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1. Device Name

Product code: GEI
Trade Names: Bissinger Monopolar Cables
Common Name: electrosurgical, cutting & coagulation & accessories
Classification Name: Electrosurgical cutting and coagulation device and accessories.

2. Classification Product Code / Subsequent Code

2.1. Product Code

Device	Medical Specialty	Review Panel	Product Code	Device Class	Regulation Number
Electrosurgical cutting and coagulation device and accessories.	Part 878	General & Plastic Surgery	GEI	2	878.4400

3. Predicate Device

Bissinger's Monopolar Cables are substantially equivalent to the following predicate devices, already cleared by the FDA:

Predicate Device	510(k) Number	510(k) Holder
Hans Hermann Laparoscopes and Accessories	K051610	HANS HERMANN GMBH
Suffer Electrosurgical Cables	K073450	Suffer Medizintechnik GmbH

4. Description of the Device

Bissinger monopolar cables are non-sterile, reusable Monopolar Cables fitting Bovie Electrosurgical units. They are designed to conduct electrical power from the output of a high frequency generator to the instrument.

5. Indications for Use

Cables for electrosurgery are designed to conduct electrical power from the output of a high-frequency electrosurgical generator to the electrosurgical instrument.
Do not exceed a maximum output of 6250 Vp of your generator.

6. Technological Characteristics

	NEW DEVICE	Predicate Device 1	Predicate Device 2	Reference DEVICE	RESULT
510(k) Submitter/ Holder	Bissinger Medizintechnik GmbH	HANS HERMANN GMBH	Sutter Medizintechnik GmbH	Jarit Surgical Instruments Inc.	NA
Trade Name	Bissinger Monopolar Cables	Hans Hermann Laparoscopes and accessories	Sutter Electrosurgical Cables	Unipolar Endoscopic Coagulator-cutter and Accessories	NA
Device	Bissinger Monopolar Cables	Laparoscopes	Sutter Electrosurgical Cables	JARIT SURGICAL INSTRUMENTS	NA
510(k) Number	--	K051610	K073450	K932456	NA
Intended use	Cables for electrosurgery are designed to conduct electrical power from the output of a high-frequency electrosurgical generator to the electrosurgical instrument. Do not exceed a maximum output of 6250 Vp of your generator.	The Laparosopes and accessories are intended for use in providing access to and visualization ol body cavities, organs, and canals to perform various diagnostic and therapeutic surgical procedures. The arthroscope is indicated for illumination during joint examinations, arthroscopies, biopsies an(diagnosis of joint disease in minimally invasive procedures of the knee, shoulder, wrist (carpal tunnel syndrome), temporal mandibular joint, ankle and elbow. The bipolar electrodes are use to coagulate and to remove or destroy tissue by the use of bipolar HF current.	To electrically connect monopolar /bipolar electrosurgical instruments to an electrosurgical generator.	For use by, or as directed by, a surgeon in endoscopic surgery.For use in endoscopic surgery. For use when a rigid endoscopic instrument for grasping and/or dissecting if soft tissue is determined to be appropriate by the surgeon. Monopolar electrosurgical current can be used for coagulation and/or cutting as determined necessary and appropriate by the surgeon.	Substantial Equivalent
Type	Monopolar Cable	Monopolar silicone Cables	Monopolar silicone Cables	Jarit 600-290	SubstantialEquivalent

	NEW DEVICE	Predicate Device 1	Predicate Device 2	Reference DEVICE	RE-SULT
Design	Length: 3,080 m. Socket: Ø 4 mm Plug Ø 8 mm Connection: Bovie	Length: 3 m, Connector: 4 mm Connection: Erbe,, Martin, Berchtold,	Length: 3.5 mtr, 4,5 mtr. Connector: 4 mm Connection: Valleylab, Conmed, Bovie, Bowa, Erbe, K. Storz, R. Wolf, Martin, Berchtold, Aesculap	Length: 3,080 m. Socket: Ø 4 mm Plug Ø 8 mm Connection: Bovie	Sub-stan-tialEqu ivalent
Materials / Biocom-patibility	Material: Silicon Cables do not have direct contact with the human body or only with uninjured skin, so that biocompatibility must not be evaluated.	**Silicon**	**Silicon**	**Silicon**	Sub-stan-tialequ iva-lenrt
Sterility	Reusable Instruments. Delivery non sterile. The instruments must be sterilized in moist heat (Autoclave). Pre-vacuum Cycle - Temperature: 132°C - Exposure time: 4 min. - Drying time: at least 20 min.	Reusable Instru-ments. Delivery non sterile. The instruments must be sterilized in moist heat (Autoclave). Pre-vacuum Cycle - Temperature: 132°C, max 137°C - Exposure time: 3 min. - Drying time: at least 10 min.	Sutter Electrosurgical Cables are supplied non-sterile and can be reused after clean-ing and steam sterili-zation. Steam-sterilize in the autoclave in accord-ance with DIN EN 13060 / DIN EN 285. Fractioned pre-vacuum sterilization: Temperature 134 °C (273 °F), 3 minutes; max. Temperature 138 °C (280 °F), max. duration 20 minutes.	Similar: Reusable In-struments	Sub-stan-tialEqu ivalent
Compati-bility with environ-ment and other devices	Generators: Bovie	Generators: : Erbe,, Martin, Berchtold,	Generators: Erbe, Martin, Valleylab, Conmed, Berchtold, Bowie, Bowa, Aescu-lap	Generators: Bovie	Sub-stan-tialEqu ivalent
Standards met	IEC 60601-2-2: 2009	IEC 60601-2-2:2009	IEC 60601-2-2:2007	IEC 60601-2-2:2009	Sub-stan-tialEqu ivalent
Energy applied	Power maxima 6.250 Vp	Power maxima 6.250 Vp	Maximum Monopolar cablesVoltage 10000 Vpp	Power maxima 6.250 Vp	Sub-stan-tialEqu ivalent

7. Testing

Testing in order to proof safety and effectiveness of Bissinger's Monopolar Cables has been performed according to recognized consensus Standards and results are conforming to the respective requirements.

7.1. Electrical Safety

The devices subject to this submission have been tested according to the requirements of IEC 60601 and IEC 60601-2-2:2009.

7.2. Sterilization

The sterilization process has been validated under consideration of recognized standards.
Testing shows that the Products can be steam sterilized with a sufficient sterility assurance level by use of standard sterilization parameters.

7.3. Reprocessing

Reprocessability was tested and validated under consideration of recognized standards.

7.4. Manual cleaning

Manual cleaning validation was performed under consideration of recognized standards.

8. Biocompatibility

All requirements of biocompatibility are met through the composition of the used materials which demonstrate the appropriate levels of biocompatibility for its clinical use. The used materials are also used in many other medical devices and have an established history of safe use and biocompatibility outlined in ISO 10993-1.

9. Substantial Equivalence Summary / Conclusion

Based on available 510(k) information provided herein, Bissinger Monopolar Cables are considered substantial equivalent to the predicate devices in terms of indications for use, material, technology, design and performance specifications.

There are no differences between the devices which would raise new issues of safety or effectiveness.